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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

APTALIS PHARMA US, INC. and APTALIS PHARMA CANADA ULC Plaintiffs, vs. ZYDUS PHARMACEUTICALS (USA) INC., ZYDUS HEALTHCARE USA LLC, and CADILA HEALTHCARE LIMITED, Defendants.	Civil Action No. _____ **COMPLAINT FOR PATENT INFRINGEMENT**

Plaintiffs Aptalis Pharma US, Inc. and Aptalis Pharma Canada ULC (collectively, "Aptalis"), by way of complaint against Defendants Zydus Pharmaceuticals (USA), Inc. ("Zydus Pharmaceuticals"), Zydus Healthcare USA LLC ("Zydus Healthcare"), and Cadila Healthcare Limited (collectively, "Zydus"), allege as follows:

Nature Of The Action

This is an action for patent infringement under the patent laws of the United States, Title 35, United States Code, that arises out of the filing by Zydus of Abbreviated New Drug Application No. 208953 ("ANDA" or "Zydus's ANDA") with the U.S. Food and Drug Administration ("FDA") seeking approval to manufacture and sell generic mesalamine suppositories prior to the expiration of U.S. Patent No. 7,541,384 ("the '384 patent"), U.S. Patent No. 8,217,083 ("the '083 patent"), and U. S. Patent No. 8,436,051 ("the '051 patent").

Parties

1. Plaintiff Aptalis Pharma US, Inc. is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 400 Interpace Parkway, Parsippany, New Jersey 07054.

2. Aptalis Pharma Canada ULC is an unlimited liability corporation organized and existing under the Canada Business Corporations Act, having a principal place of business at 4300 Bankers Hall West, 888 – 3rd Street S.W., Calgary, Alberta, T2P 5C5, Canada.

3. Upon information and belief, Zydus Pharmaceuticals is a corporation organized and existing under the laws of New Jersey, having a principal place of business at 73 Route 31 North, Pennington, New Jersey, 08534.

4. Upon information and belief, Zydus Healthcare is a limited liability company organized and existing under the laws of New Jersey, having a principal place of business at 73 Route 31 North, Pennington, New Jersey, 08534.

5. Upon information and belief, Zydus Pharmaceuticals is a wholly-owned subsidiary of Cadila Healthcare Limited (d/b/a "Zydus Cadila"). Upon information and belief, Cadila Healthcare Limited is a corporation organized and existing under the laws of India, having its principal place of business at Zydus Tower, Satellite Cross Roads, Ahmedabad 380015, India.

6. Upon information and belief, Zydus Pharmaceuticals, Zydus Healthcare, and Cadila Healthcare Limited work in concert with each other with respect to the regulatory approval, manufacturing, marketing,

distribution, and sale of generic pharmaceutical products throughout the United States, including, without limitation, in this District.

Jurisdiction And Venue

7. This action arises under the patent laws of the United States, 35 U.S.C. § 1 et seq., including 35 U.S.C. § 271, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338.

8. Zydus is subject to personal jurisdiction in this District because, among other reasons, Zydus Pharmaceuticals and Zydus Healthcare are organized and exist under the laws of the State of New Jersey, with their principal places of business in New Jersey; Zydus regularly and systematically conducts business in New Jersey; and Zydus has purposefully directed its activities at New Jersey and purposefully availed itself of the laws of New Jersey through, among other things, direct and indirect manufacturing, marketing, sales and/or distribution of generic pharmaceutical products in this District. Upon information and belief, Zydus purposefully has conducted and continues to conduct business, directly or indirectly, in this District, and this District is a likely destination for Zydus's generic mesalamine suppositories upon approval of Zydus's ANDA by the FDA.

9. Zydus is further subject to personal jurisdiction in this District because Zydus filed its ANDA with the FDA and sent notice of its paragraph IV certification to Aptalis in New Jersey. Zydus's act of filing its ANDA and sending notice of its paragraph IV certification each provide sufficient minimum contacts with the State of New Jersey. Furthermore, upon information and belief, Zydus has previously submitted to the jurisdiction of this Court and has further previously availed itself of this Court by asserting counterclaims in other civil actions initiated in this jurisdiction.

10. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391(b), 1391(c), and/or 28 U.S.C. § 1400(b).

Factual Background

11. On information and belief, on or before December 16, 2016, Zydus submitted its ANDA to the FDA, pursuant to 21 U.S.C. § 355(j). Zydus's ANDA seeks FDA approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of generic mesalamine 1000 mg rectal suppositories ("Zydus's Proposed Product").

12. Aptalis and its affiliates manufacture and sell mesalamine 1000 mg rectal suppositories under the brand name CANASA® pursuant to New

Drug Application ("NDA") No. 021252, which was approved by the FDA. CANASA® is approved for the treatment of active ulcerative proctitis.

13. U.S. Patent No. 7,541,384 ("the '384 patent") (attached as Exhibit A), titled "Mesalamine Suppository," was duly and legally issued by the United States Patent and Trademark Office ("USPTO") on June 2, 2009.

14. U.S. Patent No. 8,217,083 ("the '083 patent") (attached as Exhibit B), titled "Mesalamine Suppository," was duly and legally issued by the USPTO on July 10, 2012.

15. U.S. Patent No. 8,436,051 ("the '051 patent") (attached as Exhibit C), titled "Mesalamine Suppository," was duly and legally issued by the USPTO on May 7, 2013.

16. Aptalis owns all rights, title, and interest in and to the '384, '083 and '051 patents, including, without limitation, the right to sue and obtain relief for past, present, and future patent infringement.

17. Pursuant to 21 U.S.C. § 355(b)(1), the '083 and '051 patents are listed for CANASA® in the FDA's publication titled "Approved Drug Products with Therapeutic Equivalence Evaluations" (commonly known as the "Orange Book").

18. On information and belief, Zydus included in its ANDA a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (a "paragraph IV

certification") that, in Zydus's opinion, the '083 and '051 patents are invalid, unenforceable and/or not infringed by Zydus's Proposed Product. Zydus sent Aptalis a notice letter stating that Zydus had included paragraph IV certifications in its ANDA with respect to the '083 and '051 patents, and that it is seeking approval of its ANDA prior to expiration of the '083 and '051 patents.

19. Zydus's notice letter contained an "Offer of Confidential Access" ("OCA"), in which Zydus purportedly offered to provide portions of its ANDA to Aptalis's outside counsel and to a single in-house attorney, but in which Zydus actually sought to impose unnecessary and burdensome restrictions on Aptalis and its counsel. After several rounds of negotiations, Zydus continued to seek to impose these significant and unreasonable limitations. For example, Zydus sought to impose a broad limitation, unlimited in duration on the ability of Aptalis's counsel to prosecute patents and engage in other patent-related activities. In addition, Zydus also sought to interfere with Aptalis's ability to consult with experts relating to this case. Zydus also attempted, improperly, to impose other burdensome and punitive conditions on Aptalis and its counsel. Plaintiffs' counsel objected to Zydus's Offer as unreasonable and requested confidential access to Zydus's ANDA on reasonable terms. As of the date of this Complaint, Zydus had not granted such access.

20. Based on its review of Zydus's paragraph IV certification and other information, Aptalis is informed and believes Zydus's ANDA infringes valid claims of the '384, '083, and '051 patents, and has therefore brought this action. Aptalis anticipates obtaining access to Zydus's ANDA and additional relevant information during the litigation.

Count I: Infringement Of U.S. Patent No. 7,541,384

21. Aptalis repeats and incorporates by reference, as if fully set forth herein, the allegations contained in paragraphs 1 through 20 above.

22. On information and belief, Zydus prepared, submitted, and filed its ANDA with the FDA under § 505(j) of the Federal Food, Drug, and Cosmetic Act ("FDCA") (codified at 21 U.S.C. § 355(j)) seeking approval to engage in the commercial manufacture, use, sale, offer for sale, marketing and/or importation into the United States of Zydus's Proposed Product before the expiration of the '384 patent.

23. Under 35 U.S.C. § 271(e)(2)(A), Zydus infringed one or more claims of the '384 patent, in violation of Aptalis's patent rights, by submitting to the FDA Zydus's ANDA that seeks approval to commercially market—before the expiration of the '384 patent—Zydus's Proposed Product.

24. The manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of Zydus's Proposed Product would directly infringe, literally and/or through the doctrine of equivalents, one or more claims of the '384 patent under, for example, 35 U.S.C. §271(a).

25. On information and belief, Zydus seeks approval of the indication for Zydus's Proposed Product that is claimed in the '384 patent. Accordingly, if the FDA approves Zydus's ANDA, the manufacture, use, offer for sale, or sale within the United States, or importation into the United States of Zydus's Proposed Product would contribute to or induce infringement, literally and/or through the doctrine of equivalents, of one or more claims of the '384 patent by users of Zydus's Proposed Product under, for example, 35 U.S.C. § 271(b) and/or 35 U.S.C. § 271(c).

26. On information and belief, Zydus knows and intends that physicians, health care providers, and/or patients will use Zydus's Proposed Product in accordance with Zydus's proposed label, and it will therefore induce infringement of one or more claims of the '384 patent, with the requisite intent under 35 U.S.C. § 271(b).

27. On information and belief, Zydus was aware of the '384 patent prior to filing its ANDA seeking authorization to commercially manufacture, use, offer for sale, and sell Zydus's Proposed Product in the United States.

28. Zydus's actions render this an exceptional case under 35 U.S.C. §285.

29. If Zydus is permitted to manufacture, use, sell, offer for sale, market and/or import Zydus's Proposed Product into the United States, Aptalis will suffer substantial and irreparable harm for which it has no adequate remedy at law, unless Zydus is enjoined by this Court.

Count II: Declaratory Judgment Of Infringement Of U.S. Patent No. 7,541,384

30. Aptalis repeats and incorporates by reference, as if fully set forth herein, the allegations contained in paragraphs 1 through 29 above.

31. On information and belief, Zydus has taken significant and concrete steps toward infringement of the '384 patent under, for example, 35 U.S.C. §271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c), including by submitting its ANDA for FDA approval of Zydus's Proposed Product, and by preparing to market and sell Zydus's Proposed Product.

32. If the FDA approves Zydus's ANDA and Zydus is permitted to manufacture, use, sell, offer for sale, market and/or import Zydus's Proposed Product into the United States, Zydus would directly infringe, literally and/or through the doctrine of equivalents, one or more claims of the '384 patent under 35 U.S.C. § 271(a), in violation of Aptalis's patent rights.

33. On information and belief, Zydus seeks approval of the indication for Zydus's Proposed Product that is claimed in the '384 patent. Accordingly, if the FDA approves Zydus's ANDA, the manufacture, use, offer for sale, or sale within the United States, or importation into the United States of Zydus's Proposed Product would contribute to or induce the infringement, literally and/or through the doctrine of equivalents, of one or more claims of the '384 patent by users of Zydus's Proposed Product under, for example, 35 U.S.C. § 271(b) and/or 35 U.S.C. § 271(c).

34. On information and belief, Zydus knows and intends that physicians, health care providers, and/or patients will use Zydus's Proposed Product in accordance with Zydus's proposed label, and will therefore induce infringement of one or more claims of the '384 patent, with the requisite intent under 35 U.S.C. § 271(b).

35. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Aptalis and Zydus as to liability for Zydus's infringement of the '384 patent claims. Zydus's actions have created in Aptalis a reasonable apprehension of irreparable harm and loss resulting from Zydus's threatened imminent actions.

36. On information and belief, Zydus was aware of the '384 patent prior to filing its ANDA seeking authorization to commercially manufacture, use, offer for sale, and sell Zydus's Proposed Product in the United States.

37. Zydus's actions render this an exceptional case under 35 U.S.C. § 285.

38. Aptalis will suffer substantial and irreparable harm for which it has no adequate remedy at law, unless Zydus is enjoined by this Court.

Count III: Infringement Of U.S. Patent No. 8,217,083

39. Aptalis repeats and incorporates by reference, as if fully set forth herein, the allegations contained in paragraphs 1 through 38 above.

40. On information and belief, Zydus prepared, submitted, and filed its ANDA with the FDA under § 505(j) of the Federal Food, Drug, and Cosmetic Act ("FDCA") (codified at 21 U.S.C. § 355(j)) seeking approval to engage in the commercial manufacture, use, sale, offer for sale, marketing and/or importation into the United States of Zydus's Proposed Product before the expiration of the '083 patent.

41. On information and belief, Zydus included in its ANDA a paragraph IV certification that, in its opinion, the '083 patent is invalid, unenforceable and/or not infringed by Zydus's Proposed Product.

42. Under 35 U.S.C. § 271(e)(2)(A), Zydus infringed one or more claims of the '083 patent, in violation of Aptalis's patent rights, by submitting to the FDA Zydus's ANDA that seeks approval to commercially market Zydus's Proposed Product before the expiration of the '083 patent.

43. The manufacture, use, offer for sale, or sale within the United States, or import into the United States of Zydus's Proposed Product would directly infringe, literally and/or through the doctrine of equivalents, one or more claims of the '083 patent under, for example, 35 U.S.C. § 271(a).

44. On information and belief, Zydus seeks approval of the indication for Zydus's Proposed Product that is claimed in the '083 patent. Accordingly, if the FDA approves Zydus's ANDA, the manufacture, use, offer for sale, or sale within the United States, or importation into the United States of Zydus's Proposed Product would contribute to or induce the infringement, literally and/or through the doctrine of equivalents, of one or more claims of the '083 patent by users of Zydus's Proposed Product under, for example, 35 U.S.C. § 271(b) and/or 35 U.S.C. § 271(c).

45. On information and belief, Zydus knows and intends that physicians, health care providers, and/or patients will use Zydus's Proposed Product in accordance with Zydus's proposed label, and it will therefore

induce infringement of one or more claims of the '083 patent, with the requisite intent under 35 U.S.C. § 271(b).

46. On information and belief, Zydus was aware of the '083 patent prior to filing its ANDA seeking authorization to commercially manufacture, use, offer for sale, and sell Zydus's Proposed Product in the United States.

47. Zydus's actions render this an exceptional case under 35 U.S.C. §285.

48. If Zydus is permitted to manufacture, use, sell, offer for sale, market and/or import Zydus's Proposed Product into the United States, Aptalis will suffer substantial and irreparable harm for which it has no adequate remedy at law, unless Zydus is enjoined by this Court.

Count IV: Declaratory Judgment Of Infringement Of U.S. Patent No. 8,217,083

49. Aptalis repeats and incorporates by reference, as if fully set forth herein, the allegations contained in paragraphs 1 through 48 above.

50. On information and belief, Zydus has taken significant and concrete steps toward infringement of the '083 patent under, for example, 35 U.S.C. §271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c), including by submitting its ANDA for FDA approval of Zydus's Proposed Product, and by preparing to market and sell Zydus's Proposed Product.

51. If the FDA approves Zydus's ANDA and Zydus is permitted to manufacture, use, sell, offer for sale, market and/or import Zydus's Proposed Product into the United States, Zydus would directly infringe, literally and/or through the doctrine of equivalents, one or more claims of the '083 patent under 35 U.S.C. § 271(a), in violation of Aptalis's patent rights.

52. On information and belief, Zydus seeks approval of the indication for Zydus's Proposed Product that is claimed in the '083 patent. Accordingly, if the FDA approves Zydus's ANDA, the manufacture, use, offer for sale, or sale within the United States, or importation into the United States of Zydus's Proposed Product would contribute to or induce the infringement, literally and/or through the doctrine of equivalents, of one or more claims of the '083 patent by users of Zydus's Proposed Product under, for example, 35 U.S.C. § 271(b) and/or 35 U.S.C. § 271(c).

53. On information and belief, Zydus knows and intends that physicians, health care providers, and/or patients will use Zydus's Proposed Product in accordance with Zydus's proposed label, and will therefore induce infringement of one or more claims of the '083 patent, with the requisite intent under 35 U.S.C. § 271(b).

54. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Aptalis and Zydus as to liability

for Zydus's infringement of the '083 patent claims. Zydus's actions have created in Aptalis a reasonable apprehension of irreparable harm and loss resulting from Zydus's threatened imminent actions.

55. On information and belief, Zydus was aware of the '083 patent prior to filing its ANDA seeking authorization to commercially manufacture, use, offer for sale, and sell Zydus's Proposed Product in the United States.

56. Zydus's actions render this an exceptional case under 35 U.S.C. §285.

57. Aptalis will suffer substantial and irreparable harm for which it has no adequate remedy at law, unless Zydus is enjoined by this Court.

Count V: Infringement Of U.S. Patent No. 8,436,051

58. Aptalis repeats and incorporates by reference, as if fully set forth herein, the allegations contained in paragraphs 1 through 57 above.

59. On information and belief, Zydus prepared, submitted, and filed its ANDA with the FDA under § 505(j) of the Federal Food, Drug, and Cosmetic Act ("FDCA") (codified at 21 U.S.C. § 355(j)) seeking approval to engage in the commercial manufacture, use, sale, offer for sale, marketing and/or import into the United States of Zydus's Proposed Product before the expiration of the '051 patent.

60. On information and belief, Zydus included in its ANDA a paragraph IV certification that, in its opinion, the '051 patent is invalid, unenforceable and/or not infringed by Zydus's Proposed Product.

61. Under 35 U.S.C. § 271(e)(2)(A), Zydus infringed one or more claims of the '051 patent, in violation of Aptalis's patent rights, by submitting to the FDA Zydus's ANDA that seeks approval to commercially market Zydus's Proposed Product before the expiration of the '051 patent.

62. The manufacture, use, offer for sale, or sale within the United States, or importation into the United States of Zydus's Proposed Product would directly infringe, literally and/or through the doctrine of equivalents, one or more claims of the '051 patent under, for example, 35 U.S.C. § 271(a).

63. On information and belief, Zydus seeks approval of the indication for Zydus's Proposed Product that is claimed in the '051 patent. Accordingly, if the FDA approves Zydus's ANDA, the manufacture, use, offer for sale, or sale within the United States, or importation into the United States of Zydus's Proposed Product would contribute to or induce the infringement, literally and/or through the doctrine of equivalents, of one or more claims of the '051 patent by users of Zydus's Proposed Product under, for example, 35 U.S.C. §271(b) and/or 35 U.S.C. § 271(c).

64. On information and belief, Zydus knows and intends that physicians, health care providers, and/or patients will use Zydus's Proposed Product in accordance with Zydus's proposed label, and it will therefore induce infringement of one or more claims of the '051 patent, with the requisite intent under 35 U.S.C. § 271(b).

65. On information and belief, Zydus was aware of the '051 patent prior to filing its ANDA seeking authorization to commercially manufacture, use, offer for sale, and sell Zydus's Proposed Product in the United States.

66. Zydus's actions render this an exceptional case under 35 U.S.C. §285.

67. If Zydus is permitted to manufacture, use, sell, offer for sale, market and/or import Zydus's Proposed Product into the United States, Aptalis will suffer substantial and irreparable harm for which it has no adequate remedy at law, unless Zydus is enjoined by this Court.

Count VI: Declaratory Judgment Of Infringement Of U.S. Patent No. 8,436,051

68. Aptalis repeats and incorporates by reference, as if fully set forth herein, the allegations contained in paragraphs 1 through 67 above.

69. On information and belief, Zydus has taken significant and concrete steps toward infringement of the '051 patent under, for example, 35

U.S.C. §271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c), including by submitting its ANDA for FDA approval of Zydus's Proposed Product, and by preparing to market and sell Zydus's Proposed Product.

70. If the FDA approves Zydus's ANDA and Zydus is permitted to manufacture, use, sell, offer for sale, market and/or import Zydus's Proposed Product into the United States, Zydus would directly infringe, literally and/or through the doctrine of equivalents, one or more claims of the '051 patent under 35 U.S.C. § 271(a), in violation of Aptalis's patent rights.

71. On information and belief, Zydus seeks approval of the indication for Zydus's Proposed Product that is claimed in the '051 patent. Accordingly, if the FDA approves Zydus's ANDA, the manufacture, use, offer for sale, or sale within the United States, or importation into the United States of Zydus's Proposed Product would contribute to or induce the infringement, literally and/or through the doctrine of equivalents, of one or more claims of the '051 patent by users of Zydus's Proposed Product under, for example, 35 U.S.C. § 271(b) and/or 35 U.S.C. § 271(c).

72. On information and belief, Zydus knows and intends that physicians, health care providers, and/or patients will use Zydus's Proposed Product in accordance with Zydus's proposed label, and will therefore induce

infringement of one or more claims of the '051 patent, with the requisite intent under 35U.S.C. § 271(b).

73. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Aptalis and Zydus as to liability for Zydus's infringement of the '051 patent claims. Zydus's actions have created in Aptalis a reasonable apprehension of irreparable harm and loss resulting from Zydus's threatened imminent actions.

74. On information and belief, Zydus was aware of the '051 patent prior to filing its ANDA seeking authorization to commercially manufacture, use, offer for sale, and sell Zydus's Proposed Product in the United States.

75. Zydus's actions render this an exceptional case under 35 U.S.C. §285.

76. Aptalis will suffer substantial and irreparable harm for which it has no adequate remedy at law, unless Zydus is enjoined by this Court.

Prayer For Relief

WHEREFORE, Aptalis respectfully requests the following relief:

A. Judgment that Zydus has infringed or will infringe one or more claims of the '384, '083, and '051 patents;

B. Judgment that the claims of the '384, '083, and '051 patents are valid and enforceable;

C. An order that, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of Zydus's ANDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) shall not be earlier than the expiration dates of the '384, '083 and '051 patents, including any extensions or exclusivities;

D. A declaratory judgment that Zydus would infringe one or more claims of the '384, '083 and/or '051 patents if it manufactures, uses, sells, offers to sell, markets and/or imports into the United States Zydus's Proposed Products prior to the expiration of the '384, '083 and '051 patents, including any extensions or exclusivities;

E. A declaratory judgment that the commercial manufacture, use, sale, offer for sale and/or importation in the United States of Zydus's Proposed Products by Zydus would induce and/or contribute to third-party infringement of the '384, '083 and '051 patents;

F. Pursuant to 35 U.S.C. § 271(e)(4)(B), an injunction restraining and enjoining Zydus and its officers, agents, attorneys and employees, and those acting in privity or concert with Zydus, from engaging in the commercial manufacture, use, offer for sale, sale, marketing and/or

importation into the United States, of Zydus's Proposed Product as claimed in one or more claims of the '384, '083 and/or '051 patents, until the expiration dates of the '384, '083 and '051 patents, including any extensions or exclusivities;

G. If Zydus commercially makes, uses, sells, or offers to sell the its Proposed Product within the United States, or imports its Proposed Product into the United States, prior to the expiration of any one of the '384, '083 and '051 patents, including any extensions, that Aptalis be awarded monetary damages for those infringing acts to the fullest extent allowed by law, and be awarded prejudgment interest based on those monetary damages;

H. Judgment that Zydus's infringement of the '384, '083 and '051 patents based on its ANDA would be willful if Zydus commercially manufactures, uses, sells, offers to sell and/or imports any products that are the subject of its ANDA prior to the expiration of the '384, '083 and '051 patents.

I. Judgment that this is an exceptional case and that Aptalis is entitled to its reasonable attorneys' fees pursuant to 35 U.S.C. § 285;

J. The costs and expenses of this action; and

K. Such other and further relief as the Court may deem just and proper.

Dated: January 30, 2017

Respectfully submitted,

By: /s David E. De Lorenzi

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